



Atty. Dkt. No. 078883-0145

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Philippa RADCLIFFE et al.

Title: TRANSGENIC ORGANISM

Appl. No.: 10/082,122

Filing Date: 02/26/2002

Examiner: Unassigned

Art Unit: 1632

RECEIVED

NOV 27 2002

TECH CENTER 1600/2900

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
Box PATENT APPLICATION
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Nov 25, 2002

By Michele M. Simkin

FOLEY & LARDNER
Customer Number: 22428



22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5538

Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

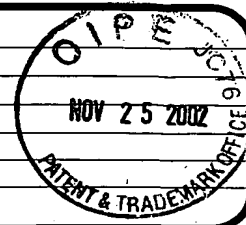
Date Submitted: November 25, 2002

(use as many sheets as necessary)

Sheet 1 of 5

Complete if Known

Application Number	10/082,122
Filing Date	02/26/2002
First Named Inventor	Philippa RADCLIFFE
Group Art Unit	1632
Examiner Name	Unassigned
Attorney Docket Number	078883-0145

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A1	WO	91/10741	A1	CELL GENESYS, INC.	07-25-1991		
	A2	WO	92/17505	A1	BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON	10-15-1992		
	A3	WO	92/21766	A1	BOEHRINGER MANNHEIM GMBH et al.	12-10-1992		
	A4	WO	95/21927	A2	ISIS INNOVATION LIMITED	08-17-1995		
	A5	WO	98/05635	A1	CHIROSCIENCE LIMITED	02-12-1998		
	A6	WO	98/07859	A2	GENETICS INSTITUTE, INC.	02-26-1998		
	A7	WO	98/09985	A2	YEDA RESEARCH AND DEVELOPMENT CO., LTD.	03-12-1998		
	A8	WO	98/15294	A1	THE UNIVERSITY OF SHEFFIELD	04-16-1998		
	A9	WO	98/17815	A1	OXFORD BIOMEDICA LIMITED	04-30-1998		
	A10	WO	99/15683	A1	OXFORD BIOMEDICA LIMITED	04-01-1999		
	A11	WO	99/32646	A1	OXFORD BIOMEDICA LIMITED	07-01-1999		
	A12	WO	99/51755	A2	THE SALK INSTITUTE FOR BIOLOGICAL STUDIES	10-14-1999		
	A13	WO	01/79518	A2	OXFORD BIOMEDICA LIMITED	10-02-2001		

RECEIVED

NOV 27 2002

TECH CENTER 1600/2900

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A14	BOWTELL et al., "Comparison of Expression in Hemopoietic Cells by Retroviral Vectors Carrying Two Genes," <u>Journal of Virology</u> , 62(7):2464-2473, American Society for Microbiology, July 1988	

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

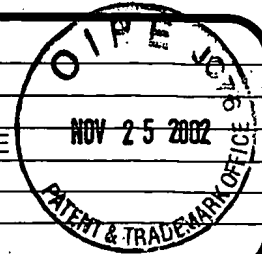
¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/082,122
		Filing Date	02/26/2002
Date Submitted: November 25, 2002		First Named Inventor	Philippa RADCLIFFE
		Group Art Unit	1632
(use as many sheets as necessary)		Examiner Name	Unassigned
		Attorney Docket Number	078883-0145
Sheet	2	of	5



OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

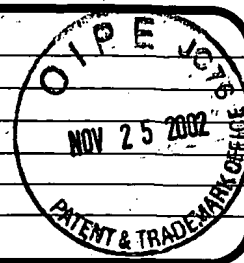
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A15	BRUCHSCHACHER & PANGANIBAN, "Human Immunodeficiency Virus Vectors for Inducible Expression of Foreign Genes," <u>Journal of Virology</u> , 66(5):2731-2739, American Society of Microbiology, May 1992	/
	A16	BRUICK & McKNIGHT, "A Conserved Family of Prolyl-4-Hydroxylases That Modify HIF," <u>Science</u> , 294:1337-1340, November 9, 2001	/
	A17	CHAN et al., "Transgenic cattle produced by reverse-transcribed gene transfer in oocytes," <u>Proc. Natl. Acad. Sci.</u> , 95:14028-14033, The National Academy of Sciences, November 1998	/
	A18	CHAN et al., "Transgenic Monkeys Produced by Retroviral Gene Transfer into Mature Oocytes," <u>Science</u> , 291:309-312, January 12, 2001	/
	A19	CLABOUGH et al., "Immune-Mediated Thrombocytopenia in Horses Infected with Equine Infectious Anemia Virus," <u>Journal of Virology</u> , 65(11):6242-6251, American Society for Microbiology, November 1991	/
	A20	COFFIN et al., "Retroviruses," pp. 683, 758-763, JM Coffin et al., eds., Cold Spring Harbour Laboratory Press, 1997	/
	A21	CORRELL et al., "Retroviral Vector Design for Long-Term Expression in Murine Hematopoietic Cells in Vivo," <u>Blood</u> , 84(6):1812-1822, The American Society of Hematology, September 15, 1994	/
	A22	CULLEN, "Regulation of HIV gene expression," <u>AIDS</u> , 9 (suppl A):S19-S32, Current Science Ltd., 1995	/
	A23	DERSE & NEWBOLD, "Mutagenesis of EIAV TAT Reveals Structural Features Essential for Transcriptional Activation and TAR Element Recognition," <u>Virology</u> , 194:530-536, Academic Press, Inc., 1993	/
	A24	DOUGHERTY & TEMIN, "A promoterless retroviral vector indicated that there are sequences in U3 required for 3' RNA processing," <u>Proc. Natl. Acad. Sci.</u> , 84:1197-1201, USA, March 1987	/
	A25	EMERMAN & TEMIN, "Genes with Promoters in Retrovirus Vectors Can Be Independently Suppressed by an Epigenetic Mechanism," <u>Cell</u> , 39:459-469, MIT, December 1984 (Part 2)	/
	A26	EPSTEIN et al., "C. elegans EGL-9 and Mammalian Homologs Define a Family of Dioxygenases that Regulate HIF by Prolyl Hydroxylation," <u>Cell</u> , 107:43-54, Cell Press, October 5, 2001	/
	A27	GHATTAS et al., "The Encephalomyocarditis Virus Internal Ribosome Entry Site Allows Efficient Coexpression of Two Genes from a Recombinant Provirus in Cultured Cells and in Embryos," <u>Molecular and Cellular Biology</u> , 11(12):5848-5859, American Society for Microbiology, December 1991	/

RECEIVED
NOV 27 2002
TECH CENTER 1800/2000

Examiner
SignatureDate
Considered

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO			Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Application Number	10/082,122
			Filing Date	02/26/2002
Date Submitted: November 25, 2002 (use as many sheets as necessary)			First Named Inventor	Philippa RADCLIFFE
			Group Art Unit	1632
Sheet 3 of 5			Examiner Name	Unassigned
			Attorney Docket Number	078883-0145



OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

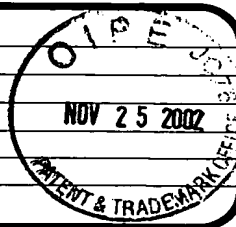
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A28	GOODCHILD & KOHLI, "Ribozymes That Cleave an RNA Sequence from Human Immunodeficiency Virus: The Effect of Flanking Sequence on Rate," <u>Archives of Biochemistry and Biophysics</u> , 284(2):386-391, Academic Press, Inc., February 1, 1991	✓
	A29	HAASS & KAHLE, "Parkin and Its Substrates," <u>Science</u> , 293:224-225, July 13, 2001	✓
	A30	HANTZOPOULOS et al., "Improved gene expression upon transfer of the adenosine deaminase minigene outside the transcriptional unit of a retroviral vector," <u>Proc. Natl. Acad. Sci.</u> , 86:3519-3523, May 1989, USA	✓
	A31	HATZOGLOU et al., "Hormonal Control of Interacting Promoters Introduced into Cells by Retroviruses," <u>The Journal of Biological Chemistry</u> , 266(13):8416-8425, The American Society for Biochemistry and Molecular Biology, Inc., May 5, 1991, USA	✓
	A32	HATZOGLOU et al., "Hormonal Regulation of Chimeric Genes Containing the Phosphoenolpyruvate Carboxykinase Promoter Regulatory Region in Hepatoma Cells Infected by Murine Retroviruses*," <u>The Journal of Biological Chemistry</u> , 263(33):17798-17808, The American Society for Biochemistry and Molecular Biology, Inc., November 25, 1988, USA	✓
	A33	HAWLEY et al., "Handicapped retroviral vectors efficiently transduce foreign genes into hematopoietic stem cells," <u>Proc. Natl. Acad. Sci.</u> , 84:2406-2410, USA, April 1987	✓
	A34	HERMAN & COFFIN, "Efficient Packaging of Readthrough RNA in ALV: Implications for Oncogene Transduction," <u>Science</u> , 236:845-848, May 15, 1987	✓
	A35	JOLLY et al., "Elements in the long terminal repeat of murine retroviruses enhance stable transformation by thymidine kinase gene," <u>Nucleic Acids Research</u> , 11(6):1855-1872, IRL Press Limited, Oxford, England, 1983	✓
	A36	KITADA et al., "Mutations in the <i>parkin</i> gene cause autosomal recessive juvenile parkinsonism," <u>Nature</u> , 392:605-608, April 9, 1998	✓
	A37	KRÜGER et al., "Ala30Pro mutation in the gene encoding α -synuclein in Parkinson's disease," <u>Nature Genetics</u> , 18:106-108, February 1998	✓
	A38	LEWIS & EMERMAN, "Passage through Mitosis Is Required for Oncoretroviruses but Not for the Human Immunodeficiency Virus," <u>Journal of Virology</u> , 68(1):510-516, American Society for Microbiology, Jan. 1994	✓
	A39	LEWIS et al., "Human immunodeficiency virus infection of cells arrested in the cell cycle," <u>The EMBO Journal</u> , 11(8):3053-3058, Oxford University Press, 1992	✓

TECH CENTER 1600/2900

Examiner Signature	Date Considered
--------------------	-----------------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/082,122
		Filing Date	02/26/2002
Date Submitted: November 25, 2002 (use as many sheets as necessary)		First Named Inventor	Philippa RADCLIFFE
		Group Art Unit	1632
Sheet 4 of 5		Examiner Name	Unassigned
		Attorney Docket Number	078883-0145



OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A40	LI et al., "Comparison of the Expression of a Mutant Dihydrofolate Reductase under Control of Different Internal Promoters in Retroviral Vectors," <u>Human Gene Therapy</u> , 3:381-390, Mary Ann Liebert, Inc., Publishers (1992)	✓
	A41	MARTARANO et al., "Equine infectious Anemia Virus <i>trans</i> -Regulatory Protein Rev Controls Viral mRNA Stability, Accumulation, and Alternative Splicing," <u>Journal of Virology</u> , 68(5):3102-3111, American Society for Microbiology, May 1994	✓
	A42	MAURY et al., "Cellular and Viral Specificity of Equine Infectious Anemia Virus Tat Transactivation," <u>Virology</u> , 200:632-642, Academic Press, Inc., 1994	✓
	A43	McLACHLIN et al., "Factors Affecting Retroviral Vector Function and Structural Integrity," <u>Virology</u> , 195:1-5, Academic Press, Inc. (1993)	✓
	A44	NAGANO et al., "Transgenic mice produced by retroviral transduction of male germ-line stem cells," <u>PNAS</u> , 98(23):13090-13095, November 6, 2001	✓
	A45	NALDINI et al., "In Vivo Gene Delivery and Stable Transduction of Nondividing Cells by a Lentiviral Vector," <u>Science</u> 272:263-267, April 12, 1996	✓
	A46	OVERELL et al., "Stably Transmitted Triple-Promoter Retroviral Vectors and Their Use in Transformation of Primary Mammalian Cells," <u>Molecular and Cellular Biology</u> , 8(4):1803-1808, American Society for Microbiology, April 1988	✓
	A47	POLYMEROPOULOS et al., "Mutation in the α -Synuclein Gene Identified in Families with Parkinson's Disease," <u>Science</u> , 276:2045-2047, June 27, 1997	✓
	A48	ROULEUX et al., "A Negative Regulatory Element of the Macrophage-Specific Human Mannose Receptor Gene Represses Its Expression in Nonmyeloid Cells," <u>Experimental Cell Research</u> , 214:113-119, Academic Press, Inc., 1994	✓
	A49	SCHARFMANN et al., "Long-term <i>in vivo</i> expression of retrovirus-mediated gene transfer in mouse fibroblast implants," <u>Proc. Natl. Acad. Sci.</u> , 88:4626-4630, USA, June 1991	✓
	A50	SHIMURA et al., "Ubiquitination of a New Form of α -Synuclein by Parkin from Human Brain: Implications for Parkinson's Disease," <u>Science</u> , 293:263-269, July 13, 2001	✓
	A51	VILE & RUSSEL, "Retroviruses as vectors," <u>British Medical Bulletin</u> , 51(1):12-30, The British Council (1995)	✓

RECEIVED
NOV 27 2002

10- R 1600/2900

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

Substitute for form 1449B/PTO

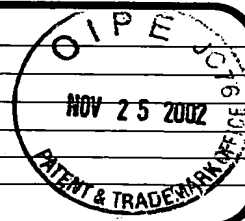
Date Submitted: November 25, 2002

(use as many sheets as necessary)

Sheet	5	of	5
-------	---	----	---

Complete if Known

Application Number	10/082,122
Filing Date	02/26/2002
First Named Inventor	Philippa RADCLIFFE
Group Art Unit	1632
Examiner Name	Unassigned
Attorney Docket Number	078883-0145

Examiner
Initials*Cite
No.¹

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

T⁶

A52 VILE et al., "A comparison of the properties of different retroviral vectors containing the murine tyrosinase promoter to achieve transcriptionally targeted expression of the HSVtk or IL-2 genes," Gene Therapy, 1:307-316. Macmillan Press, 1994

A53 VILOTTE et al., "Modification and Repression of Genes Expressed in the Mammary Gland Using Gene Targeting and Other Technologies," Journal of Mammary Gland Biology and Neoplasia, 3(3):351-362, Plenum Publishing Corporation, 1998

A54 XU et al., "Factors Affecting Long-Term Stability of Moloney Murine Leukemia Virus-Based Vectors," *Virology*, 171:331-341; Academic Press, 1989

A55 YEE et al., "A general method for the generation of high-titer, pantropic retroviral vectors: Highly efficient infection of primary hepatocytes," Proc. Natl. Acad. Sci., 91:9564-9568, USA, September 1994

A56 YEE et al., "Gene expression from transcriptionally disabled retroviral vectors," Proc. Natl. Acad. Sci. 84:5197-5201, USA, August 1987

A57 YU et al., "Self-inactivating retroviral vectors designed for transfer of whole genes into mammalian cells," Proc. Natl. Acad. Sci., 83:3194-3198, USA, May 1986

RECEIVED

NOV 27 2002

TECH CENTER 1600/2900

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁸Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁹Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, D.C. 20231.